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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CONFIRMATION I		
10/577,584	04/27/2006 Mark Jensen		21568P	7482	
210 MERCK AND	7590 04/28/200 CO., INC		EXAMINER		
PO BOX 2000			AULAKH, CHARANJIT		
RAHWAY, NJ	U/U03-U9U/		ART UNIT	PAPER NUMBER	
			1625		
			MAIL DATE	DELIVERY MODE	
			04/28/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Applicati	on No.	Applicant(s)				
		10/577,5	34	JENSEN ET AL.				
		Examine	•	Art Unit				
		Charanjit	S. Aulakh	1625				
Period fo	The MAILING DATE of this communication or Reply	appears on the	e cover sheet with the c	correspondence ac	idress			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1)	Responsive to communication(s) filed on 1	4 January 200	R					
•	Responsive to communication(s) filed on <u>14 January 2008</u> . This action is FINAL . 2b) This action is non-final.							
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
٥,١	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
4)⊠	Claim(s) 1-5 is/are pending in the application	on.						
,	4a) Of the above claim(s) is/are withdrawn from consideration.							
	i) Claim(s) is/are allowed.							
·	Claim(s) <u>1-5</u> is/are rejected.							
· ·	Claim(s) is/are objected to.							
-	Claim(s) are subject to restriction ar	nd/or election r	equirement.					
Applicati	on Papers							
9)☐ The specification is objected to by the Examiner.								
•	The drawing(s) filed on is/are: a)		objected to by the	Examiner.				
,	Applicant may not request that any objection to		-					
					FR 1.121(d).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 								
2) Notice 3) Inform	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948 mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date)	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate				

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DETAILED ACTION

1. According to paper filed on Jan. 14, 2008, the applicants have amended claims 1-5.

The applicants have also submitted a new abstract.

2. Claims 1-5 are pending in the application.

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Response to Arguments

3. Applicant's arguments filed on Jan. 14, 2008 have been fully considered but they are not persuasive regarding enablement rejection of claims 3 and 4; prior art rejection, obviousness rejection and ODP rejection. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the WO 03/093266 clearly teaches the utility of instant compounds for treating every known inflammatory and immunoregulatory disease. This publication broadly mentions the use of CCR-2 receptor modulators for treating these disorders without any specific evidence. the term --- modulating-- encompasses both agonists and antagonists of CCR-2 receptors and therefore, both agonists and antagonists can not have the identical utility. The applicants need to provide prior art references showing well established utility of CCR-2 receptor antagonists for treating every known inflammatory and immunoregulatory disorders including rheumatoid arthritis or provide references showing efficacy of CCR-2 receptor antagonists in known animal models of every known inflammatory and immunoregulatory disorder including rheumatoid arthritis.

In regard to prior art rejection, the examiner does not agree with the applicants arguments that the cited patent does not disclose the specific succinate salt claimed in the present application. Actually, succinate salt is claimed in claim 29 of this patent. In regard to obviousness rejection, the examiner does not agree with the applicants arguments that Jiao does not suggest specific salt. Jiao does teach specific salts including succinate salt as well as methods of preparing these salts on page 5.

Preparation of salts of a known compound is not a specialized field and is within the

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routine skill of an artesian. The therapeutic utility or inhibition of CCR-2 receptor activity is due to the compound itself and is not the property of any specific salt of the compound. The applicants have not provided any evidence of any specific special property of succinic salt of this compound as compared to the compound itself or other salts.

In regard to ODP rejection, the applicants mention that they will consider filing a TD.

Conclusion

- 4. Rejection of claims 3 and 4 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
- 5. Rejection of claims 1-5 under 35 U.S.C. 102(e) is maintained for the reasons of record.
- 6. Rejection of claims 1-5 under 35 U.S.C. 103(a) is maintained for the reasons of record.
- 7. The provisional ODP rejection of claims 1 and 5 is maintained for the reasons of record.
- 8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/ Primary Examiner, Art Unit 1625 Application/Control Number: 10/577,584

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